IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

-v-

10-CR-307-A

ANTHONY GALEA,

Defendant.

GOVERNMENT'S RESPONSE TO DEFENDANT'S STATEMENT REGARDING SENTENCING FACTORS [Corrected]

I. PRELIMINARY STATEMENT

On July 6, 2011, The defendant entered a guilty plea to Count III of the indictment, in which he was charged with a violation of Title 21, United States Code, Sections 331(a) and 333(a)(2) (introducing misbranded drugs into interstate commerce with intent to mislead an agency of the United States). The maximum possible sentence is a term of imprisonment of three years, and a fine of $250,000. A Pre-sentence Report (PSR), revised as of December 6, 2011, has been prepared.

On November 30, 2011, a Statement With Respect To Sentencing Factors (Docket Item #20) was filed on the defendant’s behalf. In that statement, several claims are made regarding the defendant’s conduct. The government respectfully submits that the Sentencing Statement filed on the defendant’s behalf seriously understates the

gravity of the defendant's conduct. The government files the present response in order to state its disagreement with some of the claims made on the defendant's behalf.

II. FACTS

The defendant made numerous factual admissions in paragraph 4 of the Plea Agreement. The facts are re-stated here, with language relevant to the issues discussed below highlighted in italicized bold type. The defendant's Sentencing Statement emphasizes that the guilty plea was "to a very specific regulatory offense" (*See* Item #20 at p.1). The defendant's Statement then enters into discussions concerning the status under the Food and Drug Administration (FDA) of Human Growth Hormone and Actovegin,[1] followed by a discussion of the defendant's border crossings.

The government respectfully submits that in light of the facts admitted in the Plea Agreement, the description the defense gives in the recently filed Sentencing Statement is misleading to the degree that it understates the seriousness of the offense.

[1] Human Growth Hormone (HGH) and Actovegin are two drugs identified in the Plea Agreement which the defendant distributed and dispensed in the United States for conditions for which they are not approved. HGH is approved by the FDA for use in adults only for AIDS cachexia (wasting of body tissue as a result of AIDS), short bowel syndrome, and adult onset hormonal deficiency caused by trauma to the pituitary gland.

The Factual Basis of the Plea Agreement provides as follows:

During the period of ***February 2007 through September 2009***:

a) The defendant was a citizen and resident of Canada and was a physician licensed to practice medicine in the Province of Ontario. ***The defendant was not licensed to practice medicine in the United States***. The defendant operated a medical practice in Etobicoke, Ontario, known as the Institute of Sports Medicine Health and Wellness Centre (ISM). Mary Anne Catalano was employed at ISM and worked as an assistant to the defendant.

b) The defendant traveled to the United States from Canada on numerous occasions to treat patients here. Sometimes the defendant was accompanied by Ms. Catalano to assist him; sometimes he and Ms. Catalano traveled separately and the defendant met Ms. Catalano in the United States; and on other occasions the defendant traveled to the United States alone and treated patients here without Ms. Catalano being present. Patients the defendant treated in the United States ***were professional athletes***, including but not limited to players on teams in the National Football League and Major League Baseball.

c) On ***numerous occasions the defendant and Ms. Catalano entered the United States at the Peace Bridge Port of Entry in Buffalo, New York***. ***The defendant entered the United States numerous other times via air travel from Toronto to various cities in the United States***. On some occasions, after entering the United States, the defendant traveled within the United States to different places to provide medical treatments to professional athletes. Among the places to which the defendant traveled for this purpose were Hawaii, Cleveland, New York City, Miami, Tampa, Orlando, Washington, D.C., Boston, Atlanta, San Diego, San Francisco, Denver, and Phoenix.

d) When the defendant and Ms. Catalano traveled separately to the United States, Ms. Catalano carried

medical supplies based upon a checklist she prepared based on the defendant's instructions. Some of the items on the checklist were Nutropin, Actovegin, ATP, ginseng, Celebrex, IV tubing, a centrifuge, plasma kits, and sterile gloves. ***The defendant and Ms. Catalano understood that if Ms. Catalano were asked by U.S. border officers about the purpose for her entry into the United States with the medical supplies, she would respond that she was attending a medical conference where the defendant would speak and demonstrate the use of medical supplies. The defendant and Ms. Catalano knew, however, that on the majority of the occasions they came to the United States their only purpose for coming to the U.S. was to provide medical treatments to the defendant's patients***. Some of the medical supplies the defendant and Ms. Catalano brought into the United States for these treatments, including Nutropin and Actovegin, were ***misbranded drugs*** within the meaning of U.S. law.

e) The defendant provided the treatments listed below to his patients while in the United States. Individual patients did not necessarily receive all or more than one of these treatments.

1) "Anti-inflammatory IVs," i.e., intravenous treatments involving a mixture containing Actovegin (a substance derived from calf's blood), and Adenosine Triphosphate (ATP), Traumeel, magnesium, calcium, vitamins C, B-100, B-6, and Glutathiome;

2) Plasma Rich Platelet ("PRP") treatments, which involved extracting blood from patients, spinning the blood in a centrifuge to separate the plasma from the red blood cells, and re-injecting the plasma into the patients for the purpose of accelerating the healing process.

3) Injections containing a mixture of substances including Actovegin, Traumeel, Vitamin B-12 and (in the case of chronic injuries) Zeel, as treatment for injured muscles; and

4) Injections containing a mixture of substances including Nutropin, a human growth hormone (HGH) produced by recombinant DNA

technology, Traumeel, Procaine, Zeel, and vitamin B-12 injected into the knee and given for the purpose of treating joint inflammation.

f) The defendant also from time to time, while in the United States, distributed and administered substances such as ATP for intramuscular injections. Items used for intramuscular injections were labeled in languages other than English.

g) ***Prescription items distributed by the defendant, including but not limited to Nutropin, did not bear the "RX only" symbol required by U.S. law and FDA regulations.*** Under U.S. law and FDA regulations, substances intended for use in the cure, mitigation, treatment or prevention of disease in man, and articles intended to affect the structure or function of the body of man, as well as articles intended for use as components of such items, are "misbranded" if they are not approved by the FDA and labeled in the English language. The forms of Actovegin used as ingredients in the anti-inflammatory IVs and in the injections for injured muscles were not labeled in the English language but instead were labeled in German or Russian.

h) ***Nutropin was not approved by the FDA for the uses intended by the defendant and was approved only for a limited number of uses, which did not include the treatment of adults for inflammation of joints. Actovegin was not approved by the FDA for any use.***

i) ***The defendant administered medical treatments in the United States in such places as the homes of patients and in hotel rooms.*** The cost of the treatments, travel, lodging, and other expenses for the defendant and Ms. Catalano were charged to the patients. The amount the defendant charged to the patients during the aforementioned time period was approximately $800,000. For the purposes of this Plea Agreement, the defendant and the government agree that the value of the substances provided to the patients which contained unapproved and/or misbranded substances exceeded $30,000 but did not exceed $70,000.

(j) On or about August 27, 2009, the defendant and Ms. Catalano traveled to the United States separately. Ms.

Catalano entered the United States at the Peace Bridge and the defendant traveled to the United States from Toronto by air. The purpose of the defendant's entry into the United States was to provide medical treatments to several athletes.

(k) On September 14, 2009, Mary Anne Catalano attempted to enter the United States at the Peace Bridge in Buffalo, New York, and was referred to secondary inspection. ***During secondary inspection, Ms. Catalano told an Officer from the Department of Homeland Security, Customs and Border Protection (CBP), that she was traveling to Washington, D.C. to attend a medical conference with her employer, the defendant. Ms. Catalano further stated to the CBP Officer that she had items intended for display at the medical conference***. ***Ms. Catalano made these statements pursuant to an understanding she had with the defendant that she would falsely tell U.S. border personnel that she and the defendant would be attending a medical conference in the United States.*** A duffle bag in Ms. Catalano's vehicle contained medical items such as needles, syringes, a centrifuge, numerous bottles, including a bottle of Nutropin and bottles of Actovegin. ***In fact Ms. Catalano's purpose for coming to the United States was to meet the defendant in Washington D.C., where the defendant was to provide medical treatment to a professional athlete***.

III. FDA Status of HGH and Actovegin

The defense makes numerous statements regarding HGH and Actovegin. See Item #20 at pp. 1-9. Many of these arguments are misleading, and some are irrelevant.

First, it is irrelevant that certain HGH treatments are lawful in Canada. They were *not* lawful in the United States. Second,

whether or not there is "widespread" use of HGH in the United States also is not relevant. The comparisons made by the defense to other physicians are irrelevant because such comparisons do nothing to prove whether such uses are lawful. The government makes no comment on the defense's reference to other doctors other than to make the general observation that not all unlawful conduct is or can be prosecuted. Moreover, the references made by the defense are to licensed practitioners who do not engage in international travel to practice medicine in places where they are not licensed.

The defense also describes the legal status of HGH in the United States as "anomalous." *See* Item #20 at p. 3. In fact, the status of HGH is far from anomalous. Unlike drugs that are "scheduled," such as cocaine, heroin, and marijuana, HGH is treated separately and specifically, in Title 21, United States Code, Section 333(e). A five-year maximum penalty is prescribed for its use for unapproved purposes. The penalty is ten years if the misuse involves a minor. *See* United States v. Shortt, 485 F.3d 243 (4th Cir. 2007; United States v. Adler, 605 F.Supp. 2d 829 (W.D. Tex. 2009).

At page 6 of the defendant's Sentencing Statement, a curious argument is made concerning the status of Actovegin under the FDA. The defense states, "The fact that actovegin has not been *approved*

for use by the FDA does not mean that it has been *disapproved*." Under the FDCA, in order for a "new drug" to be introduced into interstate commerce, there must exist an approved application for such drug (i.e., FDA must find that the drug is safe and effective for its intended uses. The FDA is tasked with making sure that drugs approved for use on humans are safe. There are procedures for obtaining FDA approval. Drugs that have not received that approval cannot be lawfully used, as was done in this case. The defense's attempt to minimize Dr. Galea's conduct in this regard goes much too far.

IV. Border Inspections

The defense suggests at page 9 of the defendant's Sentencing Statement that the PSR discusses the defendant's border crossings in a confusing way. The defense states that Dr. Galea was given advice by "border officials" that he could enter the United States as a business visitor. The defense goes on to state (Item #20 at p. 10) that "the occasions for Dr. Galea failing to fully disclose, or misleadingly disclose" his purpose for entering the United States were "limited" to land crossings, but not airport inspections. Finally, the defense argues that Dr. Galea's misstatements were "not routine."

First, it is hardly a defense or even a mitigation to say that one's false statements at the border were confined to land borders but not airports.

Second, the defense Sentencing Statement ignores Dr. Galea's admission that he had an agreement with his assistant, Mary Anne Catalano, to make the false statements at the border that were necessary to enable her boss to treat his patients in the United States. Dr. Galea admitted in his plea agreement that he had an agreement with Ms. Catalano to falsely state why she was bringing medications and medical equipment into the United States. On numerous occasions, Ms. Catalano, traveling alone and carrying medical supplies for Dr. Galea, entered the United States on the pretext that she was attending a medical conference, when in fact her purpose (and Dr. Galea's purpose) was to treat patients in the United States. This practice was agreed upon and pre-arranged. As Dr. Galea admitted in paragraph 4(d) of the Plea Agreement:

> The defendant and Ms. Catalano understood that if Ms. Catalano were asked by U.S. border officers about the purpose for her entry into the United States with the medical supplies, she would respond that she was attending a medical conference where the defendant would speak and demonstrate the use of medical supplies. The defendant and Ms. Catalano knew, however, that on the majority of the occasions they came to the United States their only purpose for coming to the U.S. was to provide medical treatments to the defendant's patients.

The defense cites several occasions when he underwent secondary inspections, and suggests that the results of these inspections imparted a belief in him that his conduct was unexceptionable. *See* Item #20 at p. 10.[2] First, it is not necessarily true that a Customs inspector would recognize that a given substance was not FDA approved. Second, whatever the defendant had in his bags at these times, his purpose to practice medicine in the United States (not to attend medical conferences) still made him inadmissible here.

Regarding the defense's description of occasions when the defendant underwent secondary inspections (s*ee* Item #20 at pp. 10-11), the government responds as follows:

November 27, 2006. On this occasion, the notation made by the secondary officer was that "Subject owns I.S.M. Health and Wellness in Toronto, Ont. ... He is going down to get consultations to his clinic in Canada. He gets paid by football players when they come up for medical treatment at his clinic." The government notes that this is prior to the period covered by the charges in this case. More important, however, the purpose indicated for coming to the United States is consultations regarding a medical practice located in Toronto, where, presumably, the doctor would practice medicine.

[2] The defense's recounting of crossings for which officer notations exist come from discovery provided by the government in this case.

This does nothing to indicate U.S. government approval for Dr. Galea to practice medicine on patients in the United States, as he later was to do, and not only in Baltimore on one patient, but in many U.S. cities on scores of patients.

January 8, 2007. The defendant's reference to this entry (Item #20 at p. 11) is incomplete. The defendant omits the primary inspector's notation: "Consultant on site for the Baltimore Ravens. No work authorization." The defense also contends, without a supporting notation, that "his bags were necessarily inspected" on this entry or the previous one. In fact, there is no indication on the border crossing reports for the crossings on November 27, 2006 or January 8, 2007, that Dr. Galea's bags were inspected. They may have been inspected, and they may not have been. The records do not indicate whether or not an inspection of the bags took place.

December 18, 2007. The notations made regarding this entry show a random referral. No notations of any interest were recorded by the inspector. The record is not clear whether or not baggage was inspected. The government would note, however, that on random referrals, bags are generally examined. Still, as noted above, a Customs officer conducting such an inspection would not necessarily examine every article, nor would the officer necessarily recognize if a substance was not approved by the FDA.

February 4, 2009. Similar to the crossing on December 18, 2007, this was a random search. The report specifically indicates that the subject's bags were examined.

April 10, 2009; June 21, 2009; August 26, 2009. These three crossings are random referrals at the Toronto airport, with unremarkable findings. There were baggage inspections on these occasions.

An interesting omission from the defense's review of the secondary examination reports of Dr. Galea's crossings relates to a crossing that occurred on February 20, 2009. This was a random referral inspection, and it occurred at the Toronto airport. The inspector's notes state as follows:

> Subject was a Nexus... exam. Subject is a sports doctor who had medical equipment for a lecture he was giving in Florida. Subject decided to send the equipment a different route. Subject has many seringes[sic]/gause [sic]/application devices that were going to be used at the lecture.

This crossing fits squarely withing the pattern of Dr. Galea's illegal entries into the United States. The government's investigation shows that Dr. Galea examined and treated three

different persons in two cities on this trip, which would have left little time for attending a medical conference.[3]

A second crossing record the defense does not discuss is for September 10, 2009. This also occurred at the Toronto airport, and the Customs Officer noted that Dr. Galea was admitted as a "B1" (i.e., a visitor for business) "to teach a class in medical procedures." The government's investigation showed that Dr. Galea traveled to New York City on this day and treated two patients, and returned by air to Toronto the same day. This would have left little time to teach a class.

Practicing Without A License

The defense states that the matter of practicing without a license is "too simplistic to consider it as an aggravating factor." Item #20 at pp. 12-13. The government disagrees. Licensing is important to any profession. The comparative importance of it in the medical field is especially high. This is not to suggest that Dr. Galea was not a skilled physician, but it is necessary to be licensed *in addition to* being skilled.

[3] Thus it is not true, as the defense argues, that Dr. Galea's misleading statements occurred only at land borders and not the Toronto airport. *See* Item #20 at p. 10.

The lack of a license to practice medicine in the United States underscores the illegality of Dr. Galea's entries into this country. Dr. Galea came here numerous times over a two-year period *to work* when his pretext for coming here was to attend lectures. This is not a case in which a one-time visitor came here to do a remodeling project that required a building permit. Instead, it involves scores of entries into the country to administer medical treatments on human beings. Although we know of no examples of treatments that went wrong and resulted in injury, had that occurred, the lack of a medical license (and presumably of insurance coverage) surely would have been a serious consequence.

V. CONCLUSION

The defense has significantly understated the seriousness of the defendant's conduct. It is respectfully submitted that no basis has yet been shown that would justify a sentence below the guidelines range of 12 - 18 months.

DATED: Buffalo, New York, December 8, 2011.

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CERTIFICATE OF SERVICE

I hereby certify that on December 8, 2011, I electronically filed the **GOVERNMENT'S RESPONSE TO DEFENDANT'S STATEMENT REGARDING SENTENCING FACTORS [Corrected]**, with the Clerk of the District Court using its CM/ECF system, which would then electronically notify the following CM/ECF participants on this case:

1) Mark J. Mahoney, Esq.

2) United States Probation Department
Attn: David W. Ball, USPO

s/Laura Rogers
Laura Rogers
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